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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,589	12/28/2000	Karl Guegler	CL000861	4832

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	19

DATE MAILED: 04/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/749,589	Applicant(s) Geugler et al.
	Examiner John Ulm	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 15, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *4, 8, 9, and 24-29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4, 8, 9, and 24-29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1) Claims 4, 8, 9 and 24 to 29 are pending in the instant application. Claims 24 and 28 have been amended as requested by Applicant in Paper Number 11, filed 03 September of 2003.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) The information disclosure statement filed 10 February of 2003 fails to comply with 37 CFR 1.97© because it lacks the fee set forth in 37 CFR 1.17(p) or a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

5) Claims 4, 8, 9 and 24 to 29 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 7 of Paper Number 9. As stated therein, the instant application has provided a description of an isolated DNA encoding a putative transporter protein and the protein encoded thereby but it does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

Applicant has traversed this rejection on the premise that the claimed nucleic acid has "several uses that meet the requirements of 35 U.S.C. § 101 and the first paragraph of 35 U.S.C.

§ 112". Applicant asserts that the disclosure of an isolated nucleic acid encoding a protein which is potentially an anion transporter is, alone, sufficient to establish a utility for a specific protein and, therefore, the claimed nucleic acid. Applicant asserts that a protein of the instant invention belongs to a family of proteins of which some members are the targets of therapeutic agents and, as such, that protein has valuable commercial utilities in the drug discovery process by providing previously unidentified members of an important pharmacological target class. This argument is not persuasive because each clinical agent which has been developed by measuring its interaction with specific proteins such as receptor, proteins, transporter proteins and enzymes was evaluated against a target protein whose native physiological functions were known, such as the calcium channels, the adrenergic receptors, the dopamine receptors, the serotonin receptors, the serotonin transporters and the enzymes involves in bacterial protein and cell wall synthesis. There are also numerous proteins such as odorant receptors and calcium sensing receptors which do not appear to mediate any clinically significant process. More importantly, an artisan knew, before they employed a specific target protein to identify clinically useful compounds, which physiological process or processes they wished to manipulate and that the protein employed in their assay had an influence on that process. Even if one identifies an agonist or antagonist for a transporter protein encoded by the instant invention, this information is useless since one has no idea of what clinical effect the administration of that agonist or antagonist to an individual would have.

Applicant urges "that undue experimentation would not be required by one of ordinary skill in the art to determine which biological activities the disclosed polypeptides are involved in

so as to know how to use the claimed invention". Applicant is a advised that **no** additional experimentation is permitted if it is required to identify a specific and substantial utility for the claimed invention. Such need for additional experimentation was precluded by the court when it said that "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", " [i]t is not a reward for the search, but compensation for its successful conclusion", *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), as cited in the original rejection.

Applicant has traversed this rejection on the premise that the claimed polynucleotide can be employed as a probe, primer or chemical intermediate and the employment of that polynucleotide in this capacity is a credible, specific and substantial utility. The employment of a nucleic acid of the instant invention as a probe, primer or chemical intermediate is not a substantial or specific utility. All human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any nucleic acid encoding a protein which is expressed in a tissue specific manner can be employed as a probe to detect the tissue in which it is expressed in a sample. Alternately, a nucleic acid encoding a human protein which is expressed ubiquitously can be employed as a probe to detect the presence of any human tissue in a sample. Further, any cDNA can be employed as a probe, primer, or in a process of producing the protein

encoded thereby. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

One could just as readily argue that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these processes could be practiced without either calibration standards having known molecular structures or, at least, a range of molecular weight markers having known molecular weights. One could further extrapolate upon this premise by asserting that any item having a fixed measurable parameter can be employed to calibrate any machine or process which measures that parameter. For example, any item having a constant mass within an acceptable range can be employed to calibrate a produce scale in a grocery store. The calibration of produce scales is certainly an important function since most states require produce scales to be calibrated and certified. Therefore, to accept Applicant's arguments that any nucleic acid encoding any protein of human origin is useful as a marker would be comparable to conceding that any object of fixed mass has *prima facie* utility as a weight standard, irrespective of any other properties possessed by that object. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that

decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. Further, because that compound was a hydrocarbon it certainly could have been employed in the well known process of combustion for purposes of lighting and/ or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities, the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

To grant Applicant a patent encompassing an isolated polynucleotide encoding a naturally occurring human "anion transporter" protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *(Brenner v. Manson, Ibid)*. To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that it can be employed as a probe, primer or chemical intermediate is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a combustible fuel source.

The rejection is maintained because Applicant has failed to identify a specific and substantial utility for all anion transporter proteins or for the particular protein encoded by the

claimed nucleic acid. To employ a protein of the instant invention in the identification of compounds which act upon that protein without knowing the physiological relevant of that action is to employ the protein encoded by the claimed nucleic acid as the object of that further research which must be completed before the claimed nucleic acid is useful in currently available form. Further, even this research can not be conducted until a practitioner first makes the substantial inventive contribution of discovering a specific anion which is transported by a protein of the instant invention. The term "anion" encompasses any molecule which is negatively charged and, therefore, this term encompasses a very broad class of chemical compounds. The activity of transporter proteins is measured by employing an uptake assay in which a cell expressing a particular transporter protein is exposed to a medium containing a labeled substrate and the accumulation of the substrate in the cytoplasm of that cell is measured over a period of time. Until one knows the identity of at least one specific anion which is transported across a cell membrane by a protein of the instant invention, one can not measure the activity of that protein, as would be required to identify compounds which can act as agonists or antagonists of that protein. Therefore, contrary to Applicant's arguments, the claimed invention can not even be employed in the capacity of identifying agonists and antagonists thereto in its currently available form.

6) Claims 4, 8, 9 and 24 to 29 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Applicant's arguments filed 03 September of 2003 have been fully considered but they are not persuasive for those reasons given above.

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

a shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800